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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,087	08/24/2001	Alex Reddy Freeman	patent5_LA.doc	7265

7590 03/29/2004
ALEX FREEMAN
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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,087

Applicant(s)

FREEMAN, ALEX REDDY

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-62 is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION***Claim Rejections - 35 USC § 112***

Claims 13 – 18 and 35 – 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 13, 14, 35 and 36, the specification does not appear to teach the incorporation of a protruding peak structure within the claimed apparatus. Regarding claims 15 and 37, the specification does not appear to mention the incorporation of a collar structure. Regarding claims 16, 17 and 38, the specification does not appear to teach the incorporation of tab and recess structures for enabling the alignment of the first and second substrate. Regarding claims 18 and 39, the specification does not appear to mention the incorporation of a stop configuration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

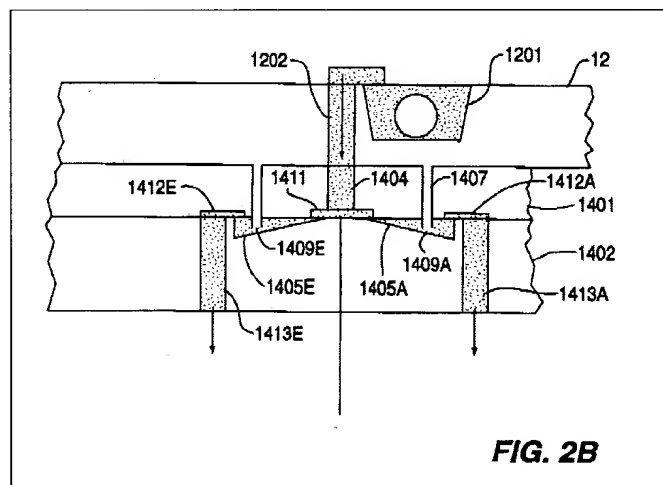
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

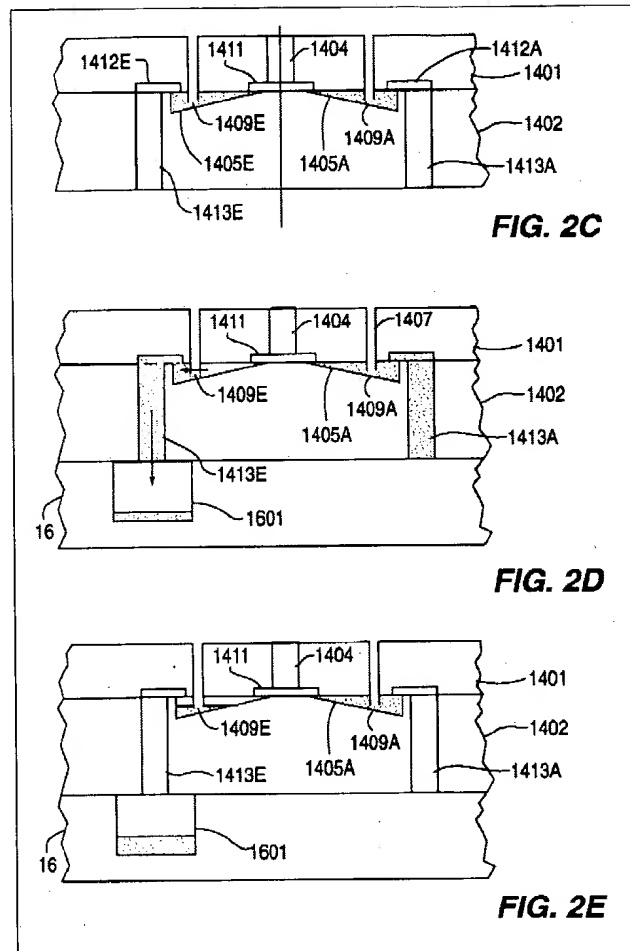
Claims 1 – 8, 21, 22, 24 – 27, 29, 30 and 42 – 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Demers (U.S. Pat. No. 5,879,632 A). Regarding claims 1 – 7, 22 and 24 – 26, and 44 – 46, Demers teaches an apparatus comprising: a first substrate (12) having at least one through-hole (1202) between the first and second surfaces of the first substrate; a second substrate (1401) having at least one microfluidic through-hole (1404) in a predetermined

Art Unit: 1743

proximate spaced position and alignment with the at least one microfluidic through-hole of the first substrate (see col. 4, line 1 – col. 5, line 40; figure 2B). Demers teaches the incorporation of electrode-based pumps and gating mechanisms to transfer fluid (see col. 4, lines 1 – 26).

Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). Regarding claims 8 and 27, Demers teaches the incorporation of a spacer portion (e.g., apportionment chamber 1405A) between the first (1401) and second (1402) substrates, which is essentially an air gap between the first and second substrates (see col. 5, lines 15 – 45; figure 2C). Regarding claim 21, the apparatus comprises a plurality of microfluidic through-holes (1202 & 1404) in each of the first (12) and second (1401) substrates (see figure 2B). Regarding claims 42 and 43, Demers teaches the incorporation of a third substrate (1402) (see figure 2B).





Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1743

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 19, 20, 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demers in view of Jedrzejewski et al. (U.S. Pat. No. 6,454,924 B2). Demers does not specifically teach the incorporation of hydrophobic upper and lower surfaces. However, Jedrzejewski et al. do teach the incorporation of hydrophobic surface treatments in microfluidic devices for facilitating effective sample fluid dispensing and transfer control (see col. 9, lines 7 – 25; col. 19, lines 47 – 67 & col. 20, lines 1 – 15). Jedrzejewski et al. additionally teach the incorporation of non-hydrophobic or hydrophilic surface treatments for controlling fluid transfer (see col. 19, lines 33 – 67; col. 20, lines 6 – 15). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of hydrophobic surface treatments, as taught by Jedrzejewski et al., with the apparatus of Demers. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of hydrophobic and hydrophilic surface treatments, as taught by Jedrzejewski et al., with the apparatus of Demers, in order to provide for effective sample fluid dispensing and transfer control.

Claims 10 – 12, 15, 31 – 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demers in view of Dubrow et al. (U.S. Pat. No. 6,251,343 B1). Regarding claims 10 – 12, Demers does not specifically teach the incorporation of tapered wall inner wall

Art Unit: 1743

surfaces. However, Dubrow et al. do teach the incorporation of tapered inner wall surfaces for the apertures of a microfluidic apparatus (see figure 2F). Dubrow et al. teach that the tapered walls allow the apertures to perform a funnel-like function, in the introduction of fluids into the ports of the microfluidic device (see col. 9, line 60 – col. 10, line 1). Specifically, wider openings facilitate the introduction of fluids into the reservoir (see col. 10, lines 1 – 4). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of tapered inner walls, as taught by Dubrow et al., with the apertures or through-holes of the Demers apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of tapered inner walls, as taught by Dubrow et al., with the apertures or through-holes of the Demers apparatus, in order to facilitate effective sample fluid transfer control. Regarding claims 15 and 37, Demers does not specifically teach the incorporation of a collar surrounding the opening of the microfluidic through-holes. However, Dubrow et al. do teach the incorporation of an annular ridge (208) surrounding each aperture (206). Dubrow et al. teach that the annular ridge provides a barrier between neighboring reservoirs in the overall device and also functions to increase the effective volume of each reservoir in the resulting device (see col. 9, lines 60 – 65). Therefore, it would have been obvious to a person of ordinary skill in the art to further incorporate the use of annular ridges or collars, as taught by Dubrow et al., around each of the microfluidic through-holes of the apparatus of Demers, in order to provide for effective sample fluid transfer control.

Art Unit: 1743

Claims 16 – 18, 23, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demers in view of Pfost et al. (U.S. Pat. No. 6,485,690 B1). Although Demers does teach that the first (1401) and second (1402) substrates are in alignment, Demers does not specifically teach the incorporation of a tab and recess or a stop configuration alignment system (see col. 4, lines 1 – 65). However, Pfost et al. do teach the use of an alignment means for a microfluidic apparatus comprising detents, flanges, or locating pins, and recessed rods, which are functionally equivalent to protruding tab structures and recesses within the substrate structures (see col. 9, lines 31 – 48). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of a tab and recess alignment means, as taught by Pfost et al., with the apparatus of Demers. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a tab and recess alignment system, as taught by Pfost et al., with the apparatus of Demers, in order to provide for the proper alignment of the first and second substrates of the apparatus.

Allowable Subject Matter

Claims 47 – 62 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The cited prior art neither teach or fairly suggest a method of transferring samples between first and second substrates, wherein the method comprises the steps of: loading a first liquid into a plurality of microfluidic through-holes disposed in the first substrate, wherein the first liquid is retained within the through-holes; loading a second liquid into a plurality of microfluidic through-holes disposed in the second substrate, wherein the second liquid is retained in the through-holes; and transferring the first liquid in the first substrate into the through-holes of the second substrate induced by meniscus contact between the first and second liquids and an applied force.

The cited prior art neither teach or fairly suggest a method comprising the steps of: loading a first test sample into a plurality of microfluidic through-holes disposed in the first substrate, wherein the first sample is retained within the through-holes; loading a reagent into a plurality of microfluidic through-holes disposed in the second substrate, wherein the reagent is retained within the through-holes; and transferring the reagent in the second substrate into the through-holes of the first substrate induced by an applied force; positioning and aligning a third substrate having a plurality of microfluidic through-holes with the microfluidic through-holes of the first substrate and forming a fluid-conducting channel in fluid communication with the through-holes of the first and third substrates between the first and third substrates; and flushing the test sample reagent mixture in the through-holes of the first substrate with a washing liquid introduced into the through-holes of the third substrate.

The cited prior art neither teach or fairly suggest a method of preparing samples, wherein the method comprises the steps of: introducing an array of samples into a first substrate retained thereby by various fluid imbalance forces; positioning a second substrate adjacent the first

Art Unit: 1743

substrate and receiving an array of spots of samples therefrom onto the second substrate; positioning a third substrate adjacent the second substrate to further create another array of samples on the second substrate; repeating the above step with additional substrates to build a library of samples on the second substrate; and positioning and aligning the second substrate with the library of samples adjacent to an assay reagent substrate having an array of assay reagents.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bass teaches a compressed loading apparatus and method for liquid transfer. Karg et al. teach a microvolume liquid dispensing array system. Bjornson et al. teach a capillary electroflow apparatus and method. Bjornson et al. also teach an apparatus and method for transferring liquids. Fisher et al. teach a method and apparatus for liquid transfer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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